April 11, 2011

Subject: Cytarabine Injection Crystallization

Dear Healthcare Professional,

Hospira is bringing to your attention the potential for Cytarabine crystallization in certain lots of the following product:

Cytarabine Injection (NDC 61703-319-22)
2 g/20 mL (100 mg/mL) vial

Cytarabine crystallization was reported with lot X061982A. Upon investigation, the crystals were determined to be particles of the active pharmaceutical ingredient. The most probable cause for the crystallization from root cause analysis is dried Cytarabine on the filling needles which may enter the vials during manufacturing, subsequently acting as a seed for crystal formation. This issue has been resolved for future production. No adverse events have been reported in connection with the crystallization issue.

Other lots that may demonstrate crystallization include:
X051982AA
Y011982AA[1]
Y021982AA[1]

Storage conditions for Cytarabine Injection are as follows:
- Protect from light. Retain in carton until time of use
- Store the product at controlled room temperature 15°-30°C (59°-86° F)

Parenteral drugs should be inspected visually for particulate matter and discoloration, prior to administration, whenever solution and container permit.

If crystals are found on inspection, the product should not be used. Do not use a filter needle or filter set to prepare or administer Cytarabine Injection which contains crystals.

For medical information, contact Hospira Medical Communications at 1-800-615-0187 or e-mail medcom@hospira.com. To report a product complaint, call 1-800-441-4100 or e-mail productcomplaintspp@hospira.com.

Sincerely,

Tariq Mir, MD
Medical Director
Global Product Safety and Complaints

[1] Note that the lot number will have a suffix of two alpha characters (i.e. AA, AB, or AC, etc.)

Hospira Inc.
275 North Field Drive
Dept. 0439, Bldg. H2-3N
Lake Forest, IL 60045
www.hospira.com